	Intermountain Forensics	SOP #	ADM-116
		Revision #	01
Forensic DNA Technical Leader Approval		Issue Date	
		08/08/2022	

Deviations

1. Purpose

Details the method for documentation of deviations from standard operating procedure or from contracts with the customer.

2. Summary

At times, the need arises for a temporary change in the specifications in testing, referred to as a deviation, performed by Intermountain Forensics. It is essential that the laboratory review the deviation prior to applying it to the procedure or the contract with the customer, to ensure that it is properly documented, technically justified, authorized by the appropriate authority, and accepted by the customer.

3. Procedure

1. Deviations to standard operating procedures must be documented in writing using DOC-117 Deviation Request Form
    a. Title the document with the following convention: Policy/Procedure Document Number_Date of Request_Case Number (if applicable) (Ex.: ADM-116_08022022_IMF-22-1234)
2. The requestor must complete the first portion of the form which includes a section to explain the technical justification for the deviation and can either request the deviation for a policy/procedure or specific to a case
    a. The technical justification for all requested deviations, including those requests made by customers, must be robust enough to support that the deviation will not impact the integrity of the laboratory or the validity of the results.
    b. If the deviation to a policy/procedure would have a beneficial long-term impact, the change should be made to the impacted policy/procedure following the document control process in a timely manner. It will be the responsibility of the DNA Technical Leader to commence the document revision.
    c. If the request is specific to a case, then the case number must be documented on the form.
3. The request must receive, at a minimum, a technical review and authorization prior to implementation
    a. The technical review and authorization will be complete by the DNA Technical Leader.
    b. A contract change review and authorization may be completed by the Director of Laboratory Development, the CEO, or a designee, as appropriate based on the scope of the request.
    c. If the deviation is applied prior to receiving appropriate authorization, the Corrective and Preventative Action Reports procedure will be implemented.
4. Customer Agreement to Deviation
    a. Submission of evidence to IMF by the customer authorizes IMF to apply the most suitable methods to complete the customer's request, based on the consultation and discussion which occurs prior to entering into the contract. As a result, IMF will be authorized to make deviations to technical processes within policies/procedures as necessary to complete processing and analysis of evidence.

   i. In the event the customer chooses to not grant this authorization as part of their contract, customer agreement must be obtained to technical deviations and the agreement documented, prior to the change being implemented.
- b. The customer agreement must be obtained and documented for all changes to a previously agreed upon scope of testing.

5. Communication of Deviation
   - a. If the deviation is case specific, the final authorizer will place a copy of this completed form in the case record.
   - b. If the deviation is policy/procedure specific, the completed Deviation Request Form will be saved in the Deviations Folder of the Shared Drive. And the DNA Technical Leader will send a notification email to all affected personnel, to communicate the change.
     i. If the only affected personnel is the requestor, no additional email will be generated.

4. References

N/A

Definitions

N/A